Complete Summary

GUIDELINE TITLE

Surgical approaches to the treatment of heart failure: HFSA 2006 comprehensive heart failure practice guideline.

BIBLIOGRAPHIC SOURCE(S)

Heart Failure Society of America. Surgical approaches to the treatment of heart failure. J Card Fail 2006 Feb; 12(1): e76-9. [27 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Heart Failure Society of America. Heart Failure Society of America (HFSA) practice guidelines. HFSA guidelines for management of patients with heart failure caused by left ventricular systolic dysfunction--pharmacological approaches. J Card Fail 1999 Dec; 5(4):357-82.

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SCOPE

DISEASE/CONDITION(S)

Heart failure

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Cardiology Internal Medicine Thoracic Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for surgical approaches to the treatment of heart failure

TARGET POPULATION

Patients with heart failure who are candidates for surgical treatment

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Heart transplantation
- 2. Mitral valve repair or replacement (not generally recommended)
- 3. Partial left ventricular resection (not recommended)
- 4. Mechanical support devices

The following emerging techniques were also discussed, but not recommended: infarct exclusion surgery, passive restraint.

MAJOR OUTCOMES CONSIDERED

- Survival rates
- Adverse events

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Databases searched included Medline and Cochrane. In addition, the guideline developers polled experts in specific areas for data.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE FVI DENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level A: Randomized, Controlled, Clinical Trials May be assigned based on results of a single trial

Level B: Cohort and Case-Control Studies Post hoc, subgroup analysis, and meta-analysis Prospective observational studies or registries

Level C: Expert Opinion Observational studies – epidemiologic findings Safety reporting from large-scale use in practice

METHODS USED TO ANALYZE THE EVI DENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Heart Failure Society of America (HFSA) Guideline Committee sought resolution of difficult cases through consensus building. Written documents were essential to this process, because they provided the opportunity for feedback from all members of the group. On occasion, consensus of Committee opinion was sufficient to override positive or negative results of almost any form or prior evidence.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

"Is recommended": Part of routine care Exceptions to therapy should be minimized.

"Should be considered": Majority of patients should receive the intervention. Some discretion in application to individual patients should be allowed.

"May be considered": Individualization of therapy is indicated

"Is not recommended": Therapeutic intervention should not be used

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The process of moving from ideas of recommendations to a final document includes many stages of evaluation and approval. Every section, once written, had a lead reviewer and 2 additional reviewers. After a rewrite, each section was assigned to another review team, which led to a version reviewed by the Committee as a whole and then the Heart Failure Society of America (HFSA) Executive Council, representing 1 more level of expertise and experience. Out of this process emerged the final document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The strength of evidence (A, B, C) and strength of recommendations are defined at the end of the "Major Recommendations" field.

Overview

• It is recommended that the decision to undertake surgical intervention for severe heart failure (HF) be made in light of functional status and prognosis based on severity of underlying HF and comorbid conditions. Procedures should be done at centers with demonstrable expertise and multidisciplinary medical and surgical teams experienced in the selection, care, and perioperative and long-term management of high risk patients with severe HF. (Strength of Evidence = C)

Specific Therapies

- Evaluation for heart transplantation is recommended in selected patients with severe HF, debilitating refractory angina, or ventricular arrhythmia that cannot be controlled despite drug, device, or alternative surgical therapy. (Strength of Evidence = B)
- Isolated mitral valve repair or replacement for severe mitral regurgitation secondary to ventricular dilatation in the presence of severe left ventricular (LV) systolic dysfunction is not generally recommended. (Strength of Evidence = C)
- Partial left ventricular resection ("Batista procedure") is not recommended in nonischemic cardiomyopathy. (Strength of Evidence = B)

- Patients awaiting heart transplantation who have become refractory to all means of medical circulatory support should be considered for a mechanical support device as a bridge to transplant. (Strength of Evidence = B)
- Permanent mechanical assistance using an implantable assist device may be considered in highly selected patients with severe HF refractory to conventional therapy who are not candidates for heart transplantation, particularly those who cannot be weaned from intravenous inotropic support at an experienced HF center. (Strength of Evidence = B)

Definitions:

Strength of Evidence

Level A: Randomized, Controlled, Clinical Trials May be assigned based on results of a single trial

Level B: Cohort and Case-Control Studies Post hoc, subgroup analysis, and meta-analysis Prospective observational studies or registries

Level C: Expert Opinion Observational studies – epidemiologic findings Safety reporting from large-scale use in practice

Strength of Recommendations

"Is recommended": Part of routine care Exceptions to therapy should be minimized.

"Should be considered": Majority of patients should receive the intervention. Some discretion in application to individual patients should be allowed.

"May be considered": Individualization of therapy is indicated

"Is not recommended": Therapeutic intervention should not be used

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations").

The recommendations are supported by randomized controlled clinical trials, cohort and case-control studies, and expert opinion.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate surgical treatment of heart failure

POTENTIAL HARMS

- Mechanical devices carry a risk of infection.
- Serious adverse events were more frequent in the left ventricular assist devices (LVAD) group in one study, predominately caused by infection, bleeding, neurologic dysfunction, and device malfunction

CONTRAINDICATIONS

CONTRAINDICATIONS

Widely accepted contraindications to cardiac transplantation include any malignancy within 5 years, diabetes mellitus with widespread microvascular complications, chronic kidney disease unlikely to reverse, irreversible pulmonary hypertension, or other medical or psychosocial issues that would impact survival.

QUALIFYING STATEMENTS

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It must be recognized that the evidence supporting recommendations is based largely on population responses that may not always apply to individuals within the population. Therefore, data may support overall benefit of 1 treatment over another but cannot exclude that some individuals within the population may respond better to the other treatment. Thus guidelines can best serve as evidence-based recommendations for management, not as mandates for management in every patient. Furthermore, it must be recognized that trial data on which recommendations are based have often been carried out with background therapy not comparable to therapy in current use. Therefore, physician decisions regarding the management of individual patients may not always precisely match the recommendations. A knowledgeable physician who integrates the guidelines with pharmacologic and physiologic insight and knowledge of the individual being treated should provide the best patient management.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Pocket Guide/Reference Cards Slide Presentation

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Heart Failure Society of America. Surgical approaches to the treatment of heart failure. J Card Fail 2006 Feb; 12(1):e76-9. [27 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 (revised 2006 Feb)

GUIDELINE DEVELOPER(S)

Heart Failure Society of America, Inc - Disease Specific Society

SOURCE(S) OF FUNDING

Heart Failure Society of America, Inc

GUI DELI NE COMMITTEE

Comprehensive Heart Failure Practice Guideline Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members and reviewers from the Executive Council received no direct financial support from the Heart Failure Society of America (HFSA) or any other source for the development of the guideline. Administrative support was provided by the Heart Failure Society of America staff, and the writing of the document was performed on a volunteer basis by the Committee. Financial relationships that might represent conflicts of interest were collected for all members of the Guideline Committee and of the Executive Council, who were asked to disclose potential conflicts and recuse themselves from discussions when necessary. Current relationships are shown in Table 1.5 of the "Development and Implementation" companion document (see the "Availability of Companion Documents" field).

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GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Heart Failure Society of America, Inc. Web site</u>.

Print copies: Available from the Heart Failure Society of America, Inc., Court International - Suite 240 S, 2550 University Avenue West, Saint Paul, Minnesota 55114; Phone: (651) 642-1633

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Heart Failure Society of America. Executive summary: HFSA 2006 comprehensive heart failure practice guideline. J Card Fail 2006 Feb; 12(1):10-38.
- Heart Failure Society of America. Development and implementation of a comprehensive heart failure practice guideline. J Card Fail 2006 Feb; 12(1): e3-9.
- Heart Failure Society of America. Conceptualization and working definition of heart failure. J Card Fail 2006 Feb; 12(1):e10-11.

Electronic copies: Available from the <u>Heart Failure Society of America, Inc. Web site.</u>

• PowerPoint slides. HFSA 2006 comprehensive heart failure guideline.

Electronic copies: Available from the <u>Heart Failure Society of America, Inc.</u> Web site.

The following is also available:

 Heart Failure Society of America. Pocket guide. HFSA 2006 comprehensive heart failure practice guideline.

Electronic copies: Not available at this time.

Print copies: Available from the Heart Failure Society of America, Inc., Court International - Suite 240 South, 2550 University Avenue West, Saint Paul, Minnesota 55114; Phone: (651) 642-1633

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 31, 2006. The information was verified by the guideline developer on August 10, 2006.

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